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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,178 | 02/05/2002 | Hiroshi Okamoto | 3914-4 | 6137 |

7590

10/02/2003

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| EXAMINER |
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LAMBERTSON, DAVID A

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| ART UNIT | PAPER NUMBER |
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1636

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DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,178

Applicant(s)

OKAMOTO, HIROSHI

Examiner

David A. Lambertson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 February 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-16 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 3-5, 7 and 14-16 (as they relate to the DNA and vector), drawn to a DNA molecule of SEQ ID NO: 1 or 3, vector comprising said sequences, host cell comprising said vectors, pharmaceutical compositions thereof, and method of making the protein encoded by said sequences.

Group II, claim(s) 2 and 14-16 (as they relate to the protein), drawn to a protein represented by SEQ ID NO: 2 or 4, and a pharmaceutical composition thereof.

Group III, claim(s) 6 and 14-16 (as they relate to the antibody), drawn to an antibody raised against the protein represented by SEQ ID NO: 2 or 4, and a pharmaceutical composition thereof.

Group IV, claim(s) 10 and 14-16 (as they relate to the compound that inhibits binding), drawn to a compound that inhibits the binding of Reg protein to the protein represented by SEQ ID NO: 2 or 4, and a pharmaceutical composition thereof.

Group V, claim(s) 13-16 (as they relate to the compound that promotes signal transduction), drawn to a compound that promotes signal transduction through the protein represented by SEQ ID NO: 2 or 4, and a pharmaceutical composition thereof.

Group VI, claim(s) 13-16 (as they relate to the compound that inhibits signal transduction), drawn to a compound that inhibits signal transduction through the protein represented by SEQ ID NO: 2 or 4, and a pharmaceutical composition thereof.

Group VII, claim(s) 8, drawn to a method of identifying a compound that binds to the protein represented by SEQ ID NO: 2 or 4.

Group VIII, claim(s) 9, drawn to a method of identifying a compound that inhibits the ability of Reg protein to bind to the protein represented by SEQ ID NO: 2 or 4.

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Group IX, claim(s) 11-12, drawn to a method of identifying a compound that promotes signal transduction through activation of the protein represented by SEQ ID NO: 2 or 4.

Group X, claim(s) 11-12, drawn to a method of identifying a compound that inhibits signal transduction through activation of the protein represented by SEQ ID NO: 2 or 4.

The inventions listed as Groups I-X do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature of invention I is the specific nucleotide sequence of SEQ ID NO: 1 and 3, the vector comprising the sequence, the host cell comprising the vector, and a method of using the sequence to make a protein.

The special technical feature of invention II is the specific amino acid sequence represented by SEQ ID NO: 2 and 4. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, whereas the function of an amino acid sequence is to perform a specific biological function. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention III is the specific amino acid sequence that represents an antibody with the ability to bind to a protein represented by SEQ ID NO: 2 or 4. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, whereas the function of an antibody is to recognize and bind to a protein. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention IV is the ability of the compound to inhibit the binding between Reg and the protein represented by SEQ ID NO: 2 and/or 4. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, whereas the function of the compound is to inhibit the binding of two proteins. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention V is the ability of the compound to promote a signal transduction event. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, whereas the function of the compound is to promote a signal transduction event. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention VI is the ability of the compound to inhibit a signal transduction event. This special technical feature is different from the special technical feature

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of invention I because the function of a nucleotide sequence is to encode a protein, whereas the function of the compound is to inhibit a signal transduction event. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention VII is the process by which a compound is identified as having the ability to bind to a protein. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, which is technically different from the identification of a compound that binds to a protein. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention VIII is the process by which a compound is identified as having the ability to inhibit binding to a protein. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, which is technically different from the identification of a compound that inhibits binding to a protein. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention IX is the process by which a compound is identified as having the ability to promote a signal transduction event. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, which is technically different from the identification of a compound that promotes signal transduction. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

The special technical feature of invention X is the process by which a compound is identified as having the ability to inhibit a signal transduction event. This special technical feature is different from the special technical feature of invention I because the function of a nucleotide sequence is to encode a protein, which is technically different from the identification of a compound that inhibits signal transduction. Because the inventions have different functions, they have different special technical features and therefore lack unity of invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (703) 308-8365. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David A. Lambertson
AU 1636


GERRY LEFFERS
PRIMARY EXAMINER